DEPARTMENT OF HEALTH AND HUMAN SERVICES

§17500

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

September 17, 2001

WARNING LETTER
CIN-WL-5019-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert N. Schmidt, President
Cleveland Medical Devices, Inc.
11000 Cedar Ave., Suite #130
Cleveland, Ohio 44106

Dear Mr. Schmidt:

During an inspection of your establishment located in Cleveland, Ohio, on July 24,26 and August 6 & 9, 2001, our investigator determined that your establishment manufactures wireless medical telemetry monitoring systems. These products are medical devices, as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The law requires that manufacturers of medical devices conform to the Quality System Regulation for medical devices as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The above stated inspection revealed that your devices are adulterated within the meaning of Section 501(h() of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation of these devices are not in conformance with the Quality System/Good Manufacturing Practice (QS/GMP) Medical Devices Regulation (21 CFR 820) as follows:

1. No evidence that the Quality Policy has been implemented, understood and maintained by all levels of the organization.

2. No management review procedures and no documented management reviews.

3. Appointment of management representatives was not documented.

4. No audit has been conducted in accordance with your procedures.

5. No training has been scheduled, conducted or documented.

6. Verification/validation of all design requirements was not documented. For example, one input requirement is the operational distance range, yet there is no data to show that the device meets this design requirement. Front end performance verification data is also missing from the Model 15 Design Index.

7. Contents of the design history file has not been signed and approved.

8. Design history file cover page was not signed and approved.

9. No documented corrective and preventative action for software bugs found during retrospective validation. Validation testing revealed several responses that were unexpected and may potentially adversely effect the performance of the Model 15 Crystal-EEG telemetry device. Yet these responses were not evaluated and addressed. These unexpected responses include the **software acceptance of a new patient under an existing patients identifier without displaying an error message** and **four other unexpected responses** documented in the Crystal Software Validation document.

10. Software validation report not reviewed, approved and signed.

11. Risk assessment revealed **numerous** unanticipated risks that have not been addressed. For example, one such risk is that the **computer unit may acquire the wrong patients data**. There were three possible causes attributed to this failure in the System Risk Assessment document, yet there is no implemented strategy to reduce the risk of these failures.

This letter is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of violations identified by the FDA. You also must promptly initiate permanent corrective action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions submissions for Class III devices to which the QS/GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations have been corrected.

You should take prompt action to correct these violations. Failure to achieve prompt correction may result in regulatory action without further notice. These include seizure and/or injunction.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other agencies and other restrictions discussed above, we are requesting that you submit to this office certification by an outside expert consultant that he/she has conducted an audit of your establishments manufacturing and quality assurance systems relative to the requirements of the device QS/GMP regulation (21CFR, Part 820). You should also submit a copy of the consultant's report, and certification by your establishment's Chief Executive Officer (if other than yourself) that he or she has reviewed the consultant's report and that your establishment has initiated or completed all corrections called for in the report. The consultant's report and your certification should be submitted to this office by April 30, 2002. The enclosed guidance may be helpful in selectuing an appropriate consultant.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct these violations.

Your response should explain each step you are taking to correct the noted violations, including steps to prevent recurrence of similar violations. Include any documentation showing these corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

We received your letter, dated August 16, 2001, in response to the Form FDA-483 issued to you at the close of the inspection. Your response does not provide adequate assurance that all of the deficiencies observed at your firm have been corrected. You provide commitments and anticipated timeframes within which you expect corrections to be completed, indicating most of these violations will be corrected by September 2001, yet you have not yet provided documentation showing that these violations have actually been corrected.

We are particularly concerned about the Design Control deficiencies noted under observations numbers 6, 9 and 11. Observation 6 pertains to the lack of design validation/verification for each specific operating requirement as reflected in your design index. Observations number 9 and 11 pertain to your failure to address and correct problems with software bugs/errors and defects identified during your retrospective software validation and retrospective risk assessment. These included problems with the software allowing the user to add a new patient under an existing identifier and the computer acquiring the wrong patients data. There were also four other unexpected software defects identified in your Crystal software validation responses which were not addressed by your firm. You indicate these defects will be reviewed in September 2001. However, You provide no justification to support your continued marketing of these products until such time as these defects and deficiencies are corrected or otherwise resolved. Please explain your reasoning in this matter and provide whatever documentation supports your position that these devices are safe to market.

Your reply should be sent to the U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237-3097, to the attention of Charles S. Price, Compliance Officer. Any questions regarding this letter may be directed to Mr. Price at telephone (513) 679-2700 extension 165.

Sincerely,

Deborah Grale
for Henry L. Fielden,
District Director,
Cincinnati District

Enclosure: Guidance document - Selecting a Consultant?